

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

**Remarks**

**Rejection Under 35 U.S.C. § 112, second paragraph**

Claim 44 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 44 was amended to clarify that the bioabsorbable material is filler material. Basis for this amendment is found in the specification as originally filed, for example on page 7, lines 25-28, and Example 4, pages 17-19.

**Rejection Under 35 U.S.C. § 103**

Claims 32-48 and 51-54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 7,198,641 to Barrows in view of US Patent No. 5,891,558 to Bell; US Patent Application Publication No. 2003/0049839 by Romero-Ortega et al. and US Patent Application Publication No. 2002/0090725 by Simpson et al. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 1 was amended to clarify that the filament has an exterior surface and a central lumen opening through the exterior surface wherein the central lumen comprises a hydrophilic interior effective to wick the cells into the filament through the opening. Basis for this amendment is found in the specification as filed, for example on page 7, lines 15-21, and in Figures 12-14. No new matter is added.

### **Legal Standard**

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the examiner: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459 (1966). This standard was recently affirmed by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

The Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). Indeed, the examiner's attention is drawn to the following quote by the Court in *KSR*:

"The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. . . . There is no necessary inconsistency between the test and the *Graham* analysis."

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"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

The Court also warned against the use of hindsight analysis in making an obviousness determination. The Court stated, "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (*KSR*, 127 S. Ct. at 1742, citing *Graham*, 383 U.S. at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 U.S.P.Q. 549 (6th Cir. 1964))).

**Analysis**

Claim 1 as amended is directed to a graft having a bioabsorbable filament having an exterior surface and a central lumen, wherein the central lumen extends through the exterior surface and comprises a hydrophilic interior effective to wick the cells into the filament, and cells capable of initiating hair follicle neogenesis comprising epidermal cells and dermal cells disposed within the lumen. None of the cited references, either alone or in combination disclose the claimed filament.

***Barrows***

Barrows is cited as disclosing a graft including a scaffold component which is a hollow filament made of one or more bioabsorbable polymers and cells from hair follicles useful for hair follicle neogenesis. This is incorrect. The passages cited by the Examiner disclose the use of poly(d,l-lactide-co-glycolide) (PLGA) with poly(ethylene glycol) (PEG) to produce a porous scaffold of PLGA. The PEG is dissolved from the mold to produce a porous scaffold. Barrows does not disclose or suggest a biosorbable filament having a central lumen with a hydrophilic interior effective to wick cells into the filament. Nor does Barrows disclose or suggest a biosorbable filament in which the hydrophilic interior has a faster rate of bioabsorption or liquefaction than the exterior of the filament.

***Bell***

Bell is cited as disclosing a graft containing dermal and epidermal cells as well as growth factors. Bell does not cure the deficiencies of Barrows. Specifically, Bell fails to disclose or suggest a biosorbable filament having a central lumen with a hydrophilic interior effective to wick cells into the filament. Nor does Bell disclose or suggest a biosorbable filament in which the hydrophilic interior that has a faster rate of bioabsorption or liquefaction than the exterior of the filament.

***Romero-Ortega***

Romero-Ortega is cited as allegedly disclosing a graft including a bioabsorbable filament having a central lumen. Applicants respectfully disagree. Romero-Ortega disclose scaffolds having conduits in them to allow cells to grow. See for example Figure 1A. In Figure 1A, fibers

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are placed in a cylindrical tube and covered with agarose. The fibers are removed to produce channels in the agarose. This resulting scaffold is not a bioabsorbable filament. Thus, Romero-Ortega fails to disclose or suggest a biosorbable filament having a central lumen with a hydrophilic interior effective to wick cells into the filament. Nor does Romero-Ortega disclose or suggest a biosorbable filament in which the hydrophilic interior that has a faster rate of bioabsorption or liquefaction than the exterior of the filament.

***Simpson et al.***

Simpson et al. was cited as disclosing cell attachment moieties such as RGD that can be used on electroprocessed collagen. Simpson et al. do not disclose or suggest a biosorbable filament having a central lumen with a hydrophilic interior effective to wick cells into the filament. Nor does Simpson et al. disclose or suggest a biosorbable filament in which the hydrophilic interior that has a faster rate of bioabsorption or liquefaction than the exterior of the filament.

***The Combination of the References***

None of the cited references, alone or in combination, disclose or suggest a graft including a bioabsorbable filament having an exterior surface and a central lumen, wherein the central lumen has a hydrophilic interior effective to wick the cells into the filament, and cells capable of initiating hair follicle neogenesis including epidermal cells and dermal cells disposed within the lumen. Barrows fails to disclose or suggest a filament having an exterior surface and a central lumen having a hydrophilic interior effective to wick the cells into the lumen. The

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remaining references fail to cure this deficiency. Thus, the cited references do not render the claims obvious.

**Double Patenting Rejection**

Claims 32-48 and 51-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent Application Serial No. 11/603,818; and claims 1-9 of U.S. Patent Application Serial No. 11/562,703; and claims 1, 5, 6, 7, 11, 12, and 13 of U.S. Patent Application Serial No. 11/107,230. Claims 32-33, 43 and 48 were rejected on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 7,198,641. Applicants respectfully traverse these rejections to the extent that they are applied to the claims as amended.

None of the claims of the cited applications or patent disclose or suggest a filament having an exterior surface and a central lumen having a hydrophilic interior effective to wick the cells into the lumen. The wicking action aids in loading the graft with cells and in positioning the cells within the graft. Accordingly, the rejection should be withdrawn.

**New Claims**

New claim 55 was added. Basis for the claim is found in the specification as originally filed, for example, page 7, lines 18-21.

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Allowance of claims 32-40 and 43-55 is respectfully solicited.

Respectfully submitted,

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